DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103836/5098

JAN 26 2007

InterMune, Inc.
Attention: Ms. Susan Vermeir
Vice President, Regulatory Affairs
3280 Bayshore Blvd.
Brisbane, CA 94005

Dear Ms. Vermeir:

Please refer to your request to supplement your biologics license application for the following:

STN	Drug Product	License No.	Letter Date	Receipt Date
BL 103836/5098	ACTIMMUNE® (Interferon gamma-1b)	1626	July 26, 2006	July 27, 2006

We acknowledge your amendment dated January 24, 2007.

This "Changes Being Effected" (CBE-0) supplemental new drug application provides for the following changes to the package insert and vial label (additions are underlined and deletions are in ~~strikethrough~~).

DESCRIPTION Section:

ACTIMMUNE is a sterile, clear, colorless solution filled in a single-use ~~dose~~ vial for subcutaneous injection.

PRECAUTIONS/General Subsection:

Isolated cases of acute serious hypersensitivity reactions have been observed in patients receiving ACTIMMUNE. ~~Acute serious hypersensitivity reactions have not been observed in patients receiving ACTIMMUNE, however,~~ If ~~if~~ such an acute reaction develops the drug should be discontinued immediately and appropriate medical therapy instituted. Transient cutaneous rashes have occurred in some patients following injection but have rarely necessitated treatment interruption.

ADVERSE REACTIONS Section:

ACTIMMUNE has also been evaluated in additional disease states in studies in which patients have generally received higher doses (>100 mcg/m^2/ three times weekly ~~day~~) administered by intramuscular injection or subcutaneous injection, or intravenous infusion. All of the previously described adverse reactions which occurred in patients with Chronic Granulomatous Disease have also been observed in patients receiving higher doses. Adverse

reactions not observed in patients with Chronic Glaucomatous ~~Disease receiving doses less than 100 mcg/m^2/day~~ but reported ~~seen rarely~~ in patients receiving *ACTIMMUNE* (Interferon gamma-1b) in other studies include: *Cardiovascular*—hypotension, syncope, tachyarrhythmia, heart block, heart failure, and myocardial infarction. *Central Nervous System*—confusion, disorientation, gait disturbance, Parkinsonian symptoms, seizure, hallucinations, and transient ischemic attacks. *Gastrointestinal*—hepatic insufficiency, gastrointestinal bleeding, and pancreatitis, including pancreatitis with fatal outcome. *Hematologic*—deep venous thrombosis and pulmonary embolism. *Immunological*-increased autoantibodies, lupus–like syndrome. *Metabolic*-hyponatremia, hyperglycemia and hypertriglyceridemia. *Pulmonary*—tachypnea, bronchospasm, and interstitial pneumonitis. Renal- reversible insufficiency. Other—chest discomfort, exacerbation of dermatomyositis.

OVERDOSAGE Section:

Central nervous system adverse reactions including decreased mental status, gait disturbance and dizziness have been observed, particularly in cancer patients receiving doses greater than 100 mcg/m2/day by intravenous or intramuscular administration. These abnormalities were reversible within a few days upon dose reduction or discontinuation of therapy. Reversible neutropenia, elevation of hepatic enzymes and of triglycerides, and thrombocytopenia have also been observed.

DOSAGE & ADMINISTRATION:

1. The formulation does not contain a preservative. A vial of ACTIMMUNE is suitable for a single-use ~~dose~~ only. The unused portion of any vial should be discarded.

2. ACTIMMUNE should not be mixed with other drugs in the same syringe.

HOW SUPPLIED Section:

ACTIMMUNE (Interferon gamma-1b) is a sterile, clear, colorless solution filled in a single-use ~~dose~~ vial for subcutaneous injection.

PRODUCT VIAL Label:

1. Revision of "~~single-dose~~ vial" to "single-use vial."

2. Revision of the Drug Product Concentration as follows: 100 mcg (2 million IU)/0.5 mL.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) submitted labeling January 24, 2007. Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

Sincerely,

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research